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A Randomized Active Controlled Clinical Trial to Assess Clinical Efficacy and Safety of Tapentadol Nasal Spray in Moderate to Severe Post-Surgical Pain

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Abstract : Background: Post-operative analgesia remains a clinical challenge, with central and peripheral sensitization playing a pivotal role in treatment-related complications and impaired quality of life. Centrally acting opioids offer poor risk benefit profile with increased intensity of gastrointestinal or central side effects and slow onset of clinical analgesia. The objective of this study was to assess the clinical feasibility of induction and maintenance therapy with Tapentadol Nasal Spray (NS) in moderate to severe acute post-operative pain. Methods: Phase III, randomized, active-controlled, non-inferiority clinical trial involving 294 cases who had undergone surgical procedures under general anesthesia or regional anesthesia. Post-surgery patients were randomized to receive either Tapentadol NS 45 mg or Tramadol 100mg IV as a bolus and subsequent 50 mg or 100 mg dose over 2-3 minutes. The frequency of administration of NS was at every 4-6 hours. At the end of 24 hrs, patients in the tramadol group who had a pain intensity score of ≥4 were switched to oral tramadol immediate release 100mg capsule until the pain intensity score reduced to <4. All patients who had achieved pain intensity ≤ 4 were shifted to a lower dose of either Tapentadol NS 22.5 mg or oral Tramadol immediate release 50mg capsule. The statistical analysis plan was envisaged as a non-inferiority trial involving comparison with Tramadol for Pain intensity difference at 60 minutes (PID60min), Sum of Pain intensity difference at 60 minutes (SPID60min), and Physician Global Assessment at 24 hrs (PGA24 hrs). Results: The per-protocol analyses involved 255 hospitalized cases undergoing surgical procedures. The median age of patients was 38.0 years. For the primary efficacy variables, Tapentadol NS was non-inferior to Inj/Oral Tramadol in relief of moderate to severe post-operative pain. On the basis of SPID60min, no clinically significant difference was observed between Tapentadol NS and Tramadol IV (1.73±2.24 vs. 1.64± 1.92, -0.09 [95% CI, -0.43, 0.60]). In the co-primary endpoint PGA24hrs, Tapentadol NS was non–inferior to Tramadol IV (2.12 ± 0.707 vs. 2.02 ±0.704, - 0.11[95% CI, -0.07, 0.28). However, on further assessment at 48hr, 72 hrs, and 120hrs, clinically superior pain relief was observed with the Tapentadol NS formulation that was statistically significant (p <0.05) at each of the time intervals. Secondary efficacy measures, including the onset of clinical analgesia and TOTPAR, showed non-inferiority to Tramadol. The safety profile and need for rescue medication were also similar in both the groups during the treatment period. The most common concomitant medications were anti-bacterial (98.3%). Conclusion: Tapentadol NS is a clinically feasible option for improved compliance as induction and maintenance therapy while offering a sustained and persistent patient response that is clinically meaningful in post-surgical settings.

Keywords : tapentadol nasal spray, acute pain, tramadol, post-operative pain
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